



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Robert A. SIKES *et al.*

Application No.: 09/933,797

Group Art Unit: 1631

Filed: August 21, 2001

Examiner: Zeman, M.

For: ISOLATION AND USE OF FETAL  
UROGENITAL SINUS EXPRESSED  
SEQUENCES

Attorney Docket No.: 9901-0012-999

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**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination on the merits, please enter the following amendments and remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to PENNIE & EDMONDS LLP Deposit Account No. 16-1150.

**THE AMENDMENTS**

Please cancel Claims 18-43, without prejudice.

Please amend claims 1-4, 12 and 13 to read as follows:

1. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising

ug093ft (SEQ ID NO: 747), ug101rcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).

2. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 95% identical to a sequence comprising ug093ft (SEQ ID NO: 747), ug101rcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).

3. (Once Amended) An isolated polynucleotide encoding a polypeptide wherein, except for from one to five conservative amino acid substitutions, said polypeptide has an amino acid sequence that is identical to a polypeptide encoded by a urogenital sinus-derived express sequence tag comprising ug093ft (SEQ ID NO: 747), ug101rcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).

4. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising ug311cons (SEQ ID NO:763).

12. (Once Amended) An isolated genetically engineered host cell containing the polynucleotide of claim 1.

13. (Once Amended) An isolated genetically engineered host cell containing the polynucleotide of claim 1 in operative association with a nucleotide regulatory element that controls expression of the polynucleotide in the host cell.

Please add new claim 44 as follows:

--44. (New) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 98% identical to a sequence comprising ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808).--

## REMARKS

Claims 1-43 were pending in this application. Claims 18-43 have been canceled, without prejudice to Applicants' right to pursue the subject matter of the canceled claims in future applications. Claims 1-4, 12, and 13 have been amended. New Claim 44 has been added to more particularly point out and distinctly claim the elected subject matter of the invention. Claims 1-17 and 44 are, therefore, pending in the instant application. A marked up version of the claims showing the amendments is attached hereto as Exhibit A. Matter that has been deleted from the claims is indicated by brackets and matter that has been added is indicated by underlining. A copy of all the claims, as amended, is attached hereto as Exhibit B.

In particular, Claims 1, 2, and 3 have been amended to correct an inadvertent recitation of the word "and" which has been replaced with the word "or". Claims 1, 2 and 3 have been amended to no longer recite the urogenital EST sequences corresponding to ug092, ug096, ugl02, ugl06, ug120, ug254, ug291, ug307, ug308, ug317, ug320, ug334, ug335, ug353, ug354, ug357, ug440, ug441, ug482, ug484, ug485, ug491, ug506, and ugsl48. Claim 3 has been amended so as to no longer recite the term "at least one conservative" and to recite instead from "one to five conservative" amino acid substitutions. Claim 3 has additionally been amended to recite the phrase "a polypeptide encoded by" in line 3 immediately before "a urogenital sinus-derived". Claims 12 and 13 have been amended to more particularly define that which Applicants regard as their invention by no longer reciting the term "cultured" and by adding the recitation of "isolated" immediately before "genetically engineered". Finally, Claims 1, 2, 3, 4, and 44 have been amended to recite the Sequence Identifier.

New Claim 44 has been added to more particularly define that which Applicants regard as their invention. In particular, Claim 44 recites "An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived

expressed sequence tag sequence at least 98% identical to a sequence comprising ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808).

These amendments are supported by the specification and claims as originally filed, and no new matter has been added. For example, the recitation of "at least 98% identity" can be found in the specification as filed at page 79, lines 26-29. Support for the recitation of ug371 can be found in the specification at page 17, line13. In particular, the support for the sequence identifiers can be found in the specification as filed at page 15, lines 2-3, and at page 71, lines 11-31 and in the sequence listing as originally filed. Entry of the amendments and remarks made herein is respectfully requested.

Applicants respectfully request entry of the above-made amendments and the foregoing remarks into the file of the instant application.

Respectfully submitted,

Date November 8, 2001

  
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**EXHIBIT A**  
**MARKED VERSION OF THE CLAIMS**  
**U.S. PATENT APPLICATION SERIAL NO. 09/933,797**

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1. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising [ug092,] ug093ft (SEQ ID NO: 747), [ug096,] ug101rcon (SEQ ID NO: 140), [ugl02, ug106, ug120, ug254, ug291, ug307, ug308,] ug311cons (SEQ ID NO:763), [ug317, ug320, ug334, ug335, ug353, ug354, ug357,] ug371f (SEQ ID NO: 778), [ug440, ug441, ug482, ug484, ug485, ug491,] ug493ors (SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505 ors (SEQ ID NO:803), [ug506, ugs148,] ugs186oft (SEQ ID NO:808), [and] or ugs194rs (SEQ ID NO:811).

2. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 95% identical to a sequence comprising [ug092,] ug093ft (SEQ ID NO: 747), [ug096,] ug101rcon (SEQ ID NO: 140), [ugl02, ug106, ug120, ug254, ug291, ug307, ug308,] ug311cons (SEQ ID NO:763), [ug317, ug320, ug334, ug335, ug353, ug354, ug357,] ug371f (SEQ ID NO: 778), [ug440, ug441, ug482, ug484, ug485, ug491,] ug493ors (SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505 ors (SEQ ID NO:803), [ug506, ugs148,] ugs186oft (SEQ ID NO:808), [and] or ugs194rs (SEQ ID NO:811).

3. (Once Amended) An isolated polynucleotide encoding a polypeptide wherein, except for [at least one] from one to five conservative amino acid substitutions, said polypeptide has an amino acid sequence that is identical to a polypeptide encoded by a urogenital sinus-derived express sequence tag comprising [ug092,] ug093ft (SEQ ID NO: 747), [ug096,] ug101rcon (SEQ ID NO: 140), [ugl02, ug106, ug120, ug254, ug291, ug307, ug308,] ug311cons (SEQ ID NO:763), [ug317, ug320, ug334, ug335, ug353, ug354, ug357,] ug371f (SEQ ID NO: 778), [ug440, ug441, ug482, ug484, ug485, ug491,] ug493ors (SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505 ors (SEQ ID NO:803), [ug506, ugs148,] ugs186oft (SEQ ID NO:808), [and] or ugs194rs (SEQ ID NO:811).

4. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising ug311cons (SEQ ID NO:763).

12. (Once Amended) [A] An isolated [cultured] genetically engineered host cell containing the polynucleotide of claim 1.

13. (Once Amended) [A] An isolated [cultured] genetically engineered host cell containing the polynucleotide of claim 1 in operative association with a nucleotide regulatory element that controls expression of the polynucleotide in the host cell.

44. (New) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 98% identical to a sequence comprising ug505ors (SEQ ID NO:803) or ugs 186oft (SEQ ID NO:808).

**EXHIBIT B**  
**THE CLAIMS WHICH WILL BE PENDING**  
**UPON ENTRY OF THE PRESENT AMENDMENT**  
**(Filed November 8, 2001)**  
**U.S. PATENT APPLICATION SERIAL NO. 09/933,797**

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1. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising ug093ft (SEQ ID NO: 747), ug10lrcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).
2. (Once Amended) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 95% identical to a sequence comprising ug093ft (SEQ ID NO: 747), ug10lrcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).
3. (Once Amended) An isolated polynucleotide encoding a polypeptide wherein, except for from one to five conservative amino acid substitutions, said polypeptide has an amino acid sequence that is identical to a polypeptide encoded by a urogenital sinus-derived express sequence tag comprising ug093ft (SEQ ID NO: 747), ug10lrcon (SEQ ID NO: 140), ug311cons (SEQ ID NO:763), ug371f (SEQ ID NO: 778), ug493ors SEQ ID NO: 797), ug494cons (SEQ ID NO:798), ug503s (SEQ ID NO: 801), ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808), or ugsl94rs (SEQ ID NO:811).
4. An isolated polynucleotide comprising a nucleotide sequence containing the urogenital sinus-derived expressed sequence tag comprising ug311cons (SEQ ID NO:763).
5. An isolated polynucleotide of claim 1 which is DNA.
6. The isolated polynucleotide of claim 1 which is cDNA.
7. The isolated polynucleotide of claim 1 which is genomic DNA.
8. The isolated polynucleotide of claim 1 which is RNA.
9. The isolated polynucleotide of claim 1 which further comprises a detectable label.
10. A polynucleotide vector containing the polynucleotide of claim 1.
11. A polynucleotide expression vector containing the polynucleotide of claim 1 in operative association with a nucleotide regulatory element that controls expression of the polynucleotide in a host cell.

12. (Once Amended) An isolated genetically engineered host cell containing the polynucleotide of claim 1.

13. (Once Amended) An isolated genetically engineered host cell containing the polynucleotide of claim 1 in operative association with a nucleotide regulatory element that controls expression of the polynucleotide in the host cell.

14. The genetically engineered host cell of claim 13 which is prokaryotic.

15. The genetically engineered host cell of claim 13 which is eukaryotic.

16. A method of producing a polypeptide urogenital sinus-derived gene product, comprising the steps of:

- (a) growing the genetically engineered host cell of claim 14 in a culture; and
- (b) collecting the polypeptide gene product from the culture.

17. A method of producing a polypeptide urogenital sinus-derived gene product, comprising the steps of:

- (a) growing the genetically engineered host cell of claim 15 in a culture; and
- (b) collecting the polypeptide gene product from the culture.

Claim 44. (New) An isolated polynucleotide comprising a nucleotide sequence having a urogenital sinus-derived expressed sequence tag sequence at least 98% identical to a sequence comprising ug505ors (SEQ ID NO:803), ugsl86oft (SEQ ID NO:808).